

CLAIMS

1 1. A method for evaluating a clinical trial protocol, comprising the steps of:
2 encoding workflow tasks of a clinical trial protocol into a database that includes data
3 objects describing protocol events and relationships among protocol events;
4 identifying an operational uncertainty in said protocol during said step of encoding;
5 associating said uncertainty with at least a particular one of said objects in said database;
6 and
7 in dependence upon said objects in said database, displaying a graphical-visual
8 representation of said protocol, said graphical-visual representation including a human-
9 perceptible indication that said particular object has an operational uncertainty associated
10 therewith.

1 2. A method according to claim 1, wherein said database is an object-oriented
2 database.

1 3. A method according to claim 1, wherein said data objects include protocol event
2 objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects.

1 4. A method according to claim 3, wherein said step of displaying comprises the
2 step of displaying each of said data objects in a color which differs depending on whether an
3 operational uncertainty is associated therewith.

1 5. A method according to claim 1, wherein said step of displaying comprises the
2 step of displaying each of said data objects in a color which differs depending on whether an
3 operational uncertainty is associated therewith.

1 6. A method according to claim 1, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 7. A method according to claim 1, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 8. A method according to claim 1, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 9. A method according to claim 1, wherein said operational uncertainty concerns a
2 temporal constraint among at least two of said protocol events.

1 10. At least one computer readable medium collectively carrying a machine readable
2 database which includes protocol data objects describing events of a clinical trial protocol and
3 relationships among protocol events of the clinical trial protocol, said database further including
4 a disambiguation comment object which identifies an operational uncertainty in said protocol,
5 said disambiguation comment object being associated with at least a particular one of said
6 objects in said database.

1 11. A medium according to claim 10, wherein said database is an object-oriented
2 database.

1 12. A medium according to claim 10, wherein said data objects include protocol
2 event objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects.

1 13. A medium according to claim 12, wherein said disambiguation comment object is
2 associated with one of said protocol event objects.

1 14. A medium according to claim 12, wherein said disambiguation comment object is
2 associated with a particular one of said temporal constraint objects.

1 15. A medium according to claim 14, wherein said operational uncertainty concerns
2 the amount of time allowed to elapse between two protocol events identified by said particular
3 temporal constraint object.

1 16. A medium according to claim 12, wherein said data objects further include
2 workflow task objects.

1 17. A medium according to claim 16, wherein each of said workflow task objects is
2 associated with at least one of said protocol event objects.

1 18. A medium according to claim 16, wherein said disambiguation comment object is
2 associated with one of said workflow task objects.

1 19. A medium according to claim 10, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 20. A medium according to claim 10, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 21. A medium according to claim 10, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 22. A medium according to claim 10, wherein said operational uncertainty concerns
2 the amount of time allowed to elapse between two of said protocol events.

1 23. At least one computer readable medium collectively carrying a machine readable
2 database which includes protocol event objects describing events of a clinical trial protocol and
3 temporal constraint objects describing temporal relationships among said protocol event objects,
4 at least a particular one of said temporal constraint objects identifying an amount of time
5 between at least two of said protocol events.

1 24. A medium according to claim 23, wherein said database is an object-oriented
2 database.

1 25. A medium according to claim 23, wherein said database further includes
2 workflow task objects.

1 26. A medium according to claim 23, wherein said amount of time describes the time
2 that a hypothetical patient is expected to take between first and second identified ones of said
3 protocol event objects.

1 27. A medium according to claim 23, wherein said particular temporal constraint
2 object identifies said amount of time by identifying at least one member of the group consisting
3 of minimum and maximum times.

1 28. A medium according to claim 27, wherein said particular temporal constraint
2 object identifies said amount of time by identifying both members of the group consisting of
3 minimum and maximum times.

1 29. A medium according to claim 28, wherein said particular temporal constraint
2 object identifies said amount of time further by identifying a base time between said minimum
3 and maximum times.

1 30. A medium according to claim 23, wherein said database further includes a
2 disambiguation comment object associated with said particular temporal constraint object, said

disambiguation comment object identifying an operational uncertainty in a particular temporal relationship identified in said temporal constraint object.

31. A medium according to claim 23, wherein said operational uncertainty comprises an inconsistency in one of said temporal relationships as specified in said protocol.

32. A medium according to claim 23, wherein said operational uncertainty comprises vagueness in one of said temporal relationships as specified in said protocol.

33. A medium according to claim 23, wherein said operational uncertainty comprises omission of one of said temporal relationships from said protocol.

34. A method for evaluating a clinical trial protocol, comprising the steps of:
encoding workflow tasks of a clinical trial protocol into a database structured according to a predetermined model, said model including slots predefined for describing respective aspects of protocol events and slots predefined for describing temporal relationships among protocol events, including amounts of time allowed between two or more protocol events; and
during said step of encoding, identifying an operational uncertainty in said protocol regarding a particular one of said amounts of time.

35. A method according to claim 34, further comprising the step of displaying a graphical-visual representation of said protocol, said graphical-visual representation including a

human-perceptible indication that said particular amount of time has an operational uncertainty associated therewith.

36. A method according to claim 34, wherein said predetermined model comprises a predetermined object class structure and said slots are organized into data objects defined by said object class structure.

37. A method according to claim 36, wherein said data objects include protocol event objects describing protocol events, and temporal constraint objects describing temporal constraints among said protocol event objects, each of said temporal constraint objects including at least one slot for identifying an amount of time allowed between two or more protocol events.

38. A method according to claim 37, further comprising the steps of:
instantiating a disambiguation data object defined according to said object class structure describing said operational uncertainty; and
associating said disambiguation data object with a temporal constraint object which includes a slot for identifying said particular amount of time.

39. A medium according to claim 34, wherein said operational uncertainty comprises an inconsistency in said particular amount of time as specified in said protocol.

40. A medium according to claim 34, wherein said operational uncertainty comprises vagueness in said particular amount of time as specified in said protocol.

1 41. A medium according to claim 34, wherein said operational uncertainty comprises
2 omission of said particular amount of time from said protocol.

1 42. A method for evaluating a clinical trial protocol, comprising the steps of:
2 encoding workflow tasks of a clinical trial protocol into a database that includes data
3 objects describing protocol events and relationships among protocol events;
4 identifying an operational uncertainty in said protocol during said step of encoding;
5 encoding said uncertainty into said database; and
6 in dependence upon said database, outputting a report setting forth the operational
7 uncertainties identified in said protocol and encoded into said database.

1 43. A method according to claim 42, further comprising the step of associating said
2 particular data object with at least one of said data objects in said database.

1 44. A method according to claim 43, wherein said data objects include protocol event
2 objects describing protocol events, and temporal constraint objects describing temporal
3 constraints among said protocol event objects,
4 and wherein said step of associating comprises the step of associating said particular data
5 object with one of said protocol event objects or one of said temporal constraint objects in said
6 database.

1 45. A method according to claim 42, wherein said database is an object-oriented
2 database.

1 46. A method according to claim 42, further comprising the step, prior to said step of
2 outputting, of sorting a list of said operational uncertainties identified in said protocol and
3 encoded into said database.

1 47. A method according to claim 42, wherein said step of outputting comprises the
2 step of outputting in tabular form the operational uncertainties identified in said protocol and
3 encoded into said database.

1 48. A method according to claim 42, wherein said operational uncertainty comprises
2 an inconsistency in said protocol.

1 49. A method according to claim 42, wherein said operational uncertainty comprises
2 an insufficiently specified parameter in said protocol.

1 50. A method according to claim 42, wherein said operational uncertainty comprises
2 an omitted parameter in said protocol.

1 51. A method according to claim 42, wherein said operational uncertainty concerns a
2 temporal constraint among at least two of said protocol events.